DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
Rockville MD 20857

Re: FLOLAN®
Docket Nos. 95E-0418 and 95E-0419

#16

MAR 28 1996

The Honorable Bruce Lehman
Assistant Secretary of Commerce and
Commissioner of Patents and Trademarks
Washington, D.C. 20231

Dear Commissioner Lehman:

This is in regard to the applications for patent term extension for U.S. Patent Nos. 4,338,325 and 4,883,812, filed by Glaxo Wellcome Inc., under 35 U.S.C. § 156 et seq. We have reviewed the dates contained in the applications and have determined the regulatory review period for FLOLAN®, the human drug product claimed by the patent.

The total length of the regulatory review period for FLOLAN® is 5,927 days. Of this time, 5,357 days occurred during the testing phase and 570 days occurred during the approval phase. These periods of time were derived from the following dates:

1. The date an exemption under subsection 505(i) of the Federal Food, Drug, and Cosmetic Act involving this drug product became effective: July 1, 1979.

   The applicant claims June 29, 1979, as the date the Investigational New Drug application (IND) became effective. However, FDA records indicate that the IND effective date was July 1, 1979, which was thirty days after FDA receipt of IND 16,459 on June 1, 1979.

2. The date the application was initially submitted with respect to the human drug product under subsection 505(b) of the Federal Food, Drug, and Cosmetic Act: February 28, 1994.

   FDA has verified the applicant's claim that the New Drug Application (NDA) for FLOLAN® (NDA 20-444) was initially submitted on February 28, 1994

3. The date the application was approved: September 20, 1995.

   FDA has verified the applicant's claim that NDA 20-444 was approved on September 20, 1995.

This determination of the regulatory review period by FDA does not take into account the effective date of the patent, nor does it exclude one-half of the testing phase as required by 35 U.S.C. § 156(c)(2).

Please let me know if we can be of further assistance.

Sincerely yours,

Stuart L. Nightingale, M.D.
Associate Commissioner
for Health Affairs

cc: David J. Levy, Ph.D.
Patent Counsel
Glaxo Wellcome Inc.
Five Moore Drive
Research Triangle Park, NC 27709